Claims

1. The use of amoxycillin trihydrate and potassium clavulanate in combination, in a weight ratio of between 6:1 and 8:1 (the weights being expressed as the free parent acids amoxycillin and clavulanic acid), in the manufacture of a medicament for treating bacterial infections in paediatric patients which medicament is administered twice daily (bid), at a dosage of between 15 and 80mg/kg/day of amoxycillin and *pro rata* amounts of clavulanic acid.

2. A use as claimed in claim 1 in which the dosage is between 20 and 75mg/kg/day of amoxycillin.

3. A use as claimed in claim 1 in which the dosage is between 20 and 70mg/kg/day of amoxycillin.

4. A use as claimed in claim 1 in which the dosage is between 40 and 70mg/kg/day of amoxycillin.

5. A use as claimed in any one of claims 1 to 4 in which the weight ratio is from about 6.5:1 to 7.5:1.

6. A use as claimed in any one of claims 1 to 5 in which the weight ratio is about 7:1.

7. A use as claimed in any one of claims 1 to 6 in which the dosage regimen is 70±10%mg/kg/day amoxycillin in combination with 10±10%mg/kg/day clavulanic acid.

8. A use as claimed in any one of claims 1 to 6 in which the dosage regimen is 45±10%mg/kg/day amoxycillin in combination with 6.4±10%mg/kg/day clavulanic acid.

9. A use as claimed in any one of claims 1 to 6 in which the dosage regimen is 35±10%mg/kg/day amoxycillin in combination with 5±10%mg/kg/day clavulanic acid.

10. A use as claimed in any one of claims 1 to 6 in which the dosage regimen is 25±10%mg/kg/day amoxycillin in combination with 3.6±10%mg/kg/day clavulanic acid.

11. A use as claimed in any one of claims 1 to 10 in which the formulation is provided as a liquid aqueous suspension.

12. A pharmaceutical formulation adapted for paediatric oral bid administration, comprising amoxycillin trihydrate and potassium clavulanate in combination, in a weight ratio of between 6:1 and 8:1 (the weights being expressed as the free parent acids amoxycillin and clavulanic acid), and which, when reconsituted, comprises amoxycillin in an amount of from 150 to 450mg/5ml of liquid aqueous suspension and clavulanic acid in an amount of from 25 to 75mg/5ml of liquid aqueous suspension.

13. A formulation as claimed in claim 12 in which the weight ratio is between 6.5:1 and 7.5:1.

14. A formulation as claimed in claim 12 in which the weight ratio is between about 7:1.

15. A formulation as claimed in any one of claims 12 to 14 in the form of a dry powder or a granule formulation for reconstitution into a suspension with water or other suitable aqueous media to form a suspension formulation.

16. A formulation as claimed in any one of claims 12 to 14 in the form of a liquid aqueous preparation.

17. A formulation as claimed in any one of claims 12 to 16 provided for administration at a dosage of from 15 to 80 mg/kg/day of amoxycillin.

18. A formulation as claimed in claim 17 provided for administration at a dosage of from 20 to 75 mg/kg/day of amoxycillin.

19. A formulation as claimed in claim 17 provided for administration at a dosage of from 20 to 70 mg/kg/day of amoxycillin.

20. A formulation as claimed in claim 17 provided for administration at a dosage of from 40 to 70 mg/kg/day of amoxycillin.

21. A formulation as claimed in claim 17 provided for administration at a dosage of 45±10% mg/kg/day amoxycillin and 6.4±10% mg/kg/day clavulanic acid.

22. A formulation as claimed in claim 17 provided for administration at a dosage of 70±10% mg/kg/day amoxycillin and 10±10% mg/kg/day clavulanic acid.

23. A formulation as claimed in claim 17 provided for administration at a dosage of 35±10% mg/kg/day amoxycillin and 5±10% mg/kg/day clavulanic acid.

24. A formulation as claimed in claim 17 provided for administration at a dosage of 25±10% mg/kg/day amoxycillin and 3.6±10% mg/kg/day clavulanic acid.

25. A formulation as claimed in any one of claims 12 to 24 provided for administration in unit doses of quantities of amoxycillin and clavulanic acid corresponding to amoxycillin : clavulanic acid ratios of 200±10% : 28.5±10%, and 400±10% : 57±10% mg/5ml.

26. A formulation as claimed in any one of claims 12 to 25 in which the proportion of amoxycillin and clavulanic acid is from 35-60 wt%, in a dry formulation for make-up with aqueous media into a suspension formulation.

27. A formulation as claimed in any one of claims 12 to 26 which is substantially free of mannitol.

28. A pharmaceutical formulation adapted for reconstitution as a liquid aqueous suspension comprising amoxycillin trihydrate and potassium clavulanate and which, when reconsituted, comprises amoxycillin in an amount 200±10% and clavulanic acid in an amount 28.5±10% or amoxycillin in an amount 400±10% and clavulanic acid in an amount 57±10% mg/5ml of liquid aqueous suspension.

29. A pharmaceutical formulation having a composition within ±10% of the formulae listed below, expressed as mg/5ml dose of reconstituted aqueous suspension:

Ingredient	mg/5ml	mg/5ml
amoxycillin trihydrate	408.0	204.0
potassium clavulanate	61.56	30.78
xanthan gum	12.5	12.5
colloidal silica	25.0	25.0
succinnic acid	0.84	0.84
orange flavour	15.0	15.0
orange flavour	11.25	11.25
golden syrup flavour	23.75	23.75
aspartame	12.5	12.5
hydroxypropylmethylcellulose	79.65	79.65
silicon dioxide	to 885.5	to 537.5.

30. A pharmaceutical formulation as claimed in any one of claims 12 to 28 for use in therapy.

31. A process for manufacturing a formulation according to any one of claims 12 to 29 comprising the step of mixing dry powdered or granulated ingredients for loading into a suitable container.